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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/020,389	10/30/2001	Paul Higham	OSTEONICS 3.0-352	2177

530 7590 10/09/2003

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EXAMINER	
FONTAINE, MONICA A	
ART UNIT	**PAPER NUMBER**
1732	

DATE MAILED: 10/09/2003

7

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/020,389	HIGHAM ET AL.	
	Examin r	Art Unit	
	Monica A Fontaine	1732	

-- The MAILING DATE of this communication appears on the cover sh t with the correspond nce address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 July 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *30 October 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

This office action is in response to the Amendment filed 14 July 2003.

The Corrected Declaration is acknowledged and accepted by the examiner.

All rejections in Paper No. 4 have been withdrawn as necessitated by amendment.

Claim Objections

Claim 26 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 21, and 24-26 are rejected under 35 U.S.C. 102(b) as being anticipated by Stoy et al (U.S. Patent 5,149,052).

Regarding Claim 1, Stoy et al., hereafter "Stoy," show that it is known to carry out a method for forming a hydrogel medical implant (Abstract) comprising preparing a polymer solution (Column 4, lines 41-44), injecting the solution into a mold (Column 6, lines 11-13;

Column 7, lines 30-32), causing said molded solution to gel (Column 6, lines 31-63), washing said molded gel in a physiological solution (Column 6, lines 64-66), dehydrating the molded gel (Column 12, lines 51-53), and packaging the implant (Column 11, lines 13-18).

Regarding Claims 21, and 24-26, Stoy shows the process as claimed as discussed in the rejection of Claim 1 above, including a method wherein (Claim 21) the gel formed is semi-crystalline (Column 8, lines 42-44), (Claim 24) the physiologic solution has an ionic charge (Column 8, lines 21-27; Column 9, lines 58-60), (Claim 25) the polymer is polyvinyl alcohol (Column 8, lines 60-68; Column 9, lines 21-23), and (Claim 26) the hydrogel is physically cross-linked (Column 5, lines 15-18).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 2-4, 8, and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stoy, in view of Refojo (U.S. Patent 4,452,776).

Regarding Claims 2 and 3, Stoy shows the process as claimed as discussed in the rejection of Claim 1 above, but does not specify a time frame for washing to take place. Refojo shows a method wherein said washing takes place for several weeks (Column 5, lines 9-12). Refojo and Stoy are combinable because they are concerned with a similar technical field, namely, that of molding hydrogel compositions. It would have been prima facie obvious to one

of ordinary skill in the art at the time the invention was made to wash Stoy's hydrogel for Refojo's time of several weeks to achieve adequate washing of the end product.

Regarding Claim 4, Stoy shows the process as claimed as discussed in the rejection of Claims 1 and 2 above, but he does not specify a specific composition of sodium chloride solution. Refojo shows a method wherein the physiologic solution is 0.9% sodium chloride solution (Column 7, lines 15-17). Although it is not specifically stated in Refojo, it would have been obvious to one of ordinary skill in the art at the time the invention was made to buffer the sodium chloride solution with phosphates in order to increase the compatibility of the implant with normal fluids present in humans.

Regarding Claim 8, Stoy shows the process as claimed as discussed in the rejection of Claim 1 above, but does not specify a post-dehydration water content amount. Refojo shows a method wherein the dehydration reduces the water content of the gel to its approximate in vivo equilibrium water content (Column 4, lines 11-16). It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to dehydrate Stoy's hydrogel implant to Refojo's water content amount in order to provide an implant whose purpose requires that water content amount.

Regarding Claim 11, Stoy shows the process as claimed as discussed in the rejection of Claims 1, 2, and 4 above, but he does not specify a washing time limit. Refojo shows a method wherein said washing in said saline solution is until no measurable amount of impurities remain in the implant (Column 4, lines 3-6). Although no time period is explicitly specified, it would have been obvious to one of ordinary skill in the art at the time the invention was made to be aware that the washing process could possibly take at least one day.

Claims 5-7, 9-10, and 13-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stoy and Refojo as applied to claims 1-4, 8, and 11 above, and further in view of Molock et al. (U.S. Patent 5,681,871).

Regarding Claim 5, Stoy shows the basic process as claimed as discussed in the rejection of Claims 1, 2, and 4 above, but does not show carbonate in his washing solution. Molock et al., hereafter "Molock," show that it is known to carry out a process wherein a saline solution further contains a potassium carbonate solution (Column 7, lines 54-60). Molock and Stoy are combinable because they are concerned with a similar technical field, namely, that of forming hydrogel implants. It would have been obvious to one of ordinary skill in the art at the time the invention was made to include Molock's potassium carbonate in Stoy's washing solution in order to make it more compatible with human fluid.

Regarding Claims 6 and 7, Stoy shows the basic process as claimed as discussed in the rejection of Claims 1, 2, 4, and 5 above, but does not specify concentrations of the washing solution. Molock shows that it is known to carry out a process wherein the potassium carbonate solution is 2 weight percent (0.14M) (Column 7, lines 54-60). Although Molock's molarity is outside of the claimed range, the difference between the Molock's molarity and the highest value of the claimed range is approximately 36%, and it is not clear what advantages would be present when using the claimed concentration instead of Molock's concentration. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use Molock's concentration during Stoy's molding process in order to provoke a desired product which results from a 0.05M potassium carbonate wash.

Regarding Claim 9, Stoy shows the basic process as claimed as discussed in the rejections of Claims 1 and 8 above, but does not include any provisions related to radiation. Molock shows that it is known to carry out a process which includes irradiating the molded gel after said washing (Figure 1). It would have been obvious to one of ordinary skill in the art at the time the invention was made to irradiate the molded gel after washing in order to test its durability in environments having radiation.

Regarding Claim 10, Stoy shows the basic process as claimed as discussed in the rejections of Claims 1 and 8 above, but does include any provisions related to radiation. Molock shows that it is known to carry out a process wherein the molded gel is hydrated to about 80% water content prior to irradiation (Column 6, lines 5-9). It would have been obvious to one of ordinary skill in the art at the time the invention was made to hydrate molded gel prior to irradiation, as in Molock, during Stoy's molding process in order to insure proper water content to prevent disintegration of the gel during irradiation.

Regarding Claim 13, Stoy shows a process for treating a hydrogel (Abstract) comprising forming a hydrogel from a polymer solution by physically cross-linking the polymer (Column 4, lines 41-44; Column 6, lines 31-63) and washing the hydrogel in a solution (Column 6, lines 64-66). Stoy does not show a washing solution including potassium carbonate. Molock shows that it is known to carry out a process wherein a hydrogel is washed with a potassium carbonate solution (Column 7, lines 54-60). It would have been obvious to one of ordinary skill in the art at the time the invention was made to include Molock's potassium carbonate in Stoy's washing solution in order to make it more compatible with human fluid.

Regarding Claim 14, Stoy shows the basic process as claimed as discussed in the rejection of Claim 13 above, but does not specify concentrations of the washing solution. Molock shows that it is known to carry out a process wherein the potassium carbonate solution is 2 weight percent (0.14M) (Column 7, lines 54-60). Although Molock's molarity is outside of the claimed range, the difference between the Molock's molarity and the highest value of the claimed range is approximately 36%, and it is not clear what advantages would be present when using the claimed concentration instead of Molock's concentration. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use Molock's concentration during Stoy's molding process in order to provoke a desired product which results from a 0.05M potassium carbonate wash.

Regarding Claims 15 and 16, Stoy shows the process as claimed as discussed in the rejection of Claims 14 and 15 above, but does not specify a time frame for washing to take place. Refojo shows a method wherein said washing takes place for up to several weeks (Column 5, lines 9-12). It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to wash Stoy's hydrogel for Refojo's time of up to several weeks to achieve adequate washing of the end product.

Regarding Claim 17, Stoy shows the basic process as claimed as discussed in the rejection of Claim 13 above, but does not show heating the washing solution. Molock shows that it is known to carry out a method wherein the washing solution is heated (Column 7, lines 54-57). It would have been obvious to one of ordinary skill in the art at the time the invention was made to heat the washing solution, as in Molock, during Stoy's molding process in order to make the solution more effective in cleansing the molded hydrogel.

Regarding Claim 18, Stoy shows the basic process as claimed as discussed in the rejection of Claims 13 and 17 above, but does not show heating the washing solution to a specific temperature. Molock shows that it is known to carry out a method wherein the washing solution is heated to 35°C (Column 7, lines 57-60). Although this temperature is not exactly the claimed temperature, it is not clear from the specification the advantage that would be present at a temperature 2 degrees Celcius higher than Molock's. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to heat the washing solution to Molock's temperature during Stoy's molding process in order to make the solution more effective in cleansing the molded hydrogel.

Regarding Claim 19, Stoy shows the basic process as claimed as discussed in the rejection of Claim 13 above, but does not show a phosphate buffered saline solution having potassium carbonated added thereto. Refojo shows a method wherein the physiologic solution is 0.9% sodium chloride solution (Column 7, lines 15-17). Although it is not specifically stated in Refojo, it would have been obvious to one of ordinary skill in the art at the time the invention was made to buffer the sodium chloride solution with phosphates in order to increase the compatibility of the implant with normal fluids present in humans. Furthermore, Molock shows that it is known to carry out a process wherein the potassium carbonate solution is 2 weight percent (0.14M) (Column 7, lines 54-60). Although Molock's molarity is outside of the claimed range, the difference between the Molock's molarity and the highest value of the claimed range is approximately 36%, and it is not clear what advantages would be present when using the claimed concentration instead of Molock's concentration. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use Molock's

concentration during Stoy's molding process in order to provoke a desired product which results from an approximately 0.05M potassium carbonate wash.

Regarding Claim 20, Stoy shows the basic process as claimed as discussed in the rejection of Claims 13 and 19 above, but does not specify concentrations of the saline solution. Molock shows that it is known to carry out a process wherein the potassium carbonate solution is 2 weight percent (0.14M) (Column 7, lines 54-60). Although Molock's molarity is outside of the claimed range, the difference between the Molock's molarity and the highest value of the claimed range is approximately 36%, and it is not clear what advantages would be present when using the claimed concentration instead of Molock's concentration. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use Molock's concentration during Stoy's molding process in order to provoke a desired product which results from a 0.05M potassium carbonate wash.

Regarding Claim 22, Stoy shows the process as claimed as discussed in the rejection of Claims 1 and 21 above, but he does not specify a specific composition of sodium chloride solution. Refojo shows a method wherein the physiologic solution is 0.9% sodium chloride solution (Column 7, lines 15-17). Although it is not specifically stated in Refojo, it would have been obvious to one of ordinary skill in the art at the time the invention was made to buffer the sodium chloride solution with phosphates in order to increase the compatibility of the implant with normal fluids present in humans.

Regarding Claim 23, Stoy shows the basic process as claimed as discussed in the rejection of Claims 1, and 21-22 above, but does not show carbonate in his washing solution. Molock et al., hereafter "Molock," show that it is known to carry out a process wherein a saline

solution further contains a potassium carbonate solution (Column 7, lines 54-60). Molock and Stoy are combinable because they are concerned with a similar technical field, namely, that of forming hydrogel implants. It would have been obvious to one of ordinary skill in the art at the time the invention was made to include Molock's potassium carbonate in Stoy's washing solution in order to make it more compatible with human fluid.

Regarding Claim 27, Stoy shows a process for treating a hydrogel (Abstract) comprising forming a hydrogel from a polymer solution (Column 4, lines 41-42) by physically cross-linking the polymer solution to form a semi-crystalline gel using a freeze-thawing technique (Column 4, lines 41-44; Column 6, lines 31-63; Column 8, lines 42-44; Column 12, lines 39-42) and washing the hydrogel in a solution (Column 6, lines 64-66). Stoy does not show a washing solution including potassium carbonate to increase crystallinity. Molock shows that it is known to carry out a process wherein a hydrogel is washed with a potassium carbonate solution (Column 7, lines 54-60). It would have been obvious to one of ordinary skill in the art at the time the invention was made to include Molock's potassium carbonate in Stoy's washing solution in order to increase the hydrogel's crystallinity and to make it more compatible with human fluid.

Regarding Claim 28, Stoy shows the basic process as claimed as discussed in the rejection of Claim 13 above, but does not show a phosphate buffered saline solution having potassium carbonated added thereto. Refojo shows a method wherein the physiologic solution is 0.9% sodium chloride solution (Column 7, lines 15-17). Although it is not specifically stated in Refojo, it would have been obvious to one of ordinary skill in the art at the time the invention was made to buffer the sodium chloride solution with phosphates in order to increase the compatibility of the implant with normal fluids present in humans. Furthermore, Molock shows

that it is known to carry out a process wherein the potassium carbonate solution is 2 weight percent (0.14M) (Column 7, lines 54-60). Although Molock's molarity is outside of the claimed range, the difference between the Molock's molarity and the highest value of the claimed range is approximately 36%, and it is not clear what advantages would be present when using the claimed concentration instead of Molock's concentration. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use Molock's concentration during Stoy's molding process in order to provoke a desired product which results from an approximately 0.05M potassium carbonate wash.

Regarding Claim 29, Stoy shows the basic process as claimed as discussed in the rejections of Claim 27 above, but does not include any provisions related to radiation. Molock shows that it is known to carry out a process which includes irradiating the molded gel after said washing (Figure 1). It would have been obvious to one of ordinary skill in the art at the time the invention was made to irradiate the molded gel after washing in order to test its durability in environments having radiation.

Regarding Claim 30, Stoy shows the process as claimed as discussed in the rejection of Claim 27 above, including a method wherein the polymer is polyvinyl alcohol (Column 8, lines 60-68; Column 9, lines 21-23), meeting applicant's claim.

Response to Arguments

Applicant's arguments with respect to claims 1-20 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The following patents are cited to further show the state of the art with regard to molding hydrogels in general:

U.S. Patent 4,173,606 to Stoy et al.

U.S. Patent 5,674,283 to Stoy

U.S. Patent 6,165,201 to Sawhney et al.

U.S. Patent 6,232,406 to Stoy

U.S. Patent 6,060,534 to Ronan et al.

U.S. Patent 6,383,609 to Annergren et al.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Monica A Fontaine whose telephone number is 703-305-7239. The examiner can normally be reached on Monday-Friday 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Colaianni can be reached on 703-305-5493. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.

Maf
September 26, 2003

MICHAEL COLAIANNI
PRIMARY EXAMINER